

REMARKS

Claims 36 and 43-61 are pending in the present application.

Applicants would like to thank Examiner Baum for the helpful and courteous discussion with their undersigned Representative on September 20, 2006. During this discussion, various amendments and arguments were discussed to address the outstanding rejections. The content of this discussion is believed to be reflected in the amendments and remarks herein. Reconsideration is respectfully requested in view of the following comments and the amendments presented herein.

The rejection of Claim 36 under 35 U.S.C. § 112, first paragraph (“written description”) is obviated in part by amendment and traversed in part.

The Office has alleged that the specification fails to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It appears that this ground of rejection is based on (a) the alleged absence of a “representative number of SOS1 nucleic acid sequences from a representative number of plants encoding a SOS1 polypeptide” and (b) the alleged absence of a specific recitation of “the essential regions of the SOS1 protein from all plants.”

The Examiner is reminded that MPEP § 2163.02 sets forth the test for the sufficiency of the written description:

An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Applicants submit that the specification provides an adequate description to allow the skilled artisan to recognize what has been invented and what is claimed is adequately described in the specification within the meaning of 35 U.S.C. § 112, first paragraph.

To this end, Applicants submit that the present specification fully provides the polynucleotide sequence of the SOS1 gene from *Arabidopsis thaliana* (i.e., SEQ ID NO: 1) and the polypeptide encoded thereby (SEQ ID NO: 2). Further, the specification provides parameters by which homology/identity can be ascertained (first full paragraph on page 9). A description of the SOS1 activity (i.e., Na⁺/H⁺ antiporter) and the characterization of the same is discussed on pages 15-17 and a characterization of the effect of the SOS1 protein on increasing salt tolerance is provided on pages 17-20. Moreover, in Table 1, Applicants provide a description of several mutant forms of SOS1.

Applicants further submit that based on the foregoing description in the specification, the skilled artisan can readily determine sequences meeting the claimed limitations. For example, when Applicants perform a sequence alignment for the full-length sequence of SEQ ID NO:2 (see the alignment report for the protein with 1146 amino acids **submitted herewith**), the following notable Na⁺/H⁺ antiporters (i.e. SOS1 homologs) were identified:

- 1) Arabidopsis (100% identity),
- 2) rice (60% identity),
- 3) tomato (64% identity),
- 4) poplar (65% identity),
- 5) sea grass (64% identity),
- 6) the moss (60% identity),
- 7) wheat (59% identity) and

8) salt cress (87% identity).

Based on the fact that SOS1 has 12 transmembranes on its N-terminal (450 a.a), Applicants performed a local sequence alignment based on this 450 a.a TM region. Notably, the sequence identity increases from 59-100% range to 71-100 range%, except for the moss SOS1 (61%). More specifically, when Applicants perform a sequence alignment for the N-terminal 450 a.a. SEQ ID NO:2 (see the alignment report for the protein with 450 amino acids **submitted herewith**), the following notable Na⁺/H⁺ antiporters (i.e. SOS1 homologs) were identified:

- 1) Arabidopsis (100% identity),
- 2) rice (75% identity),
- 3) tomato (71% identity),
- 4) poplar (75% identity),
- 5) sea grass (73% identity),
- 6) wheat (75% identity) and
- 7) the moss (61%).

Thus, this search can be used as a further refining search. In view of the foregoing, Applicants submit that the specification provides an adequate description to allow the skilled artisan to recognize what has been invented and what is claimed is adequately described in the specification within the meaning of 35 U.S.C. § 112, first paragraph.

Accordingly, withdrawal of this ground of rejection is requested.

The rejection of Claim 36 under 35 U.S.C. § 112, first paragraph (“enablement”) is obviated in part by amendment and traversed in part.

The Office has taken the position that the claimed invention is not supported by an enabling disclosure. Applicants respectfully disagree.

In the outstanding Office Action, the Examiner criticizes the use of the term “enhancing”. Applicants have amended the claims to clarify this term and to specify the relationship of the term intended thereby to the plant in which overexpression is performed.

The Examiner alleges that the specification does not enable homologs of the SOS1 polynucleotide of SEQ ID NO: 1 or the polypeptide of SEQ ID NO: 2. The Examiner has also asserted that it is not clear based on the specification how a plant with increased salt tolerance can be achieved by expressing the SOS1 gene in a plant. Applicants disagree.

At page 13, line 1 to page 16, line 30, Applicants provide a detailed explanation of how the skilled artisan may clone, express, and characterize the polynucleotides and/or polypeptides that fall within the scope of the present invention. Moreover, Applicants provide a detailed example on page 16, lines 31 to page 18, line 3 of how to assess the up-regulation of expression due to salt stress.

MPEP § 2164.01 states:

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Applicants submit that determining what sequences fall within or without the scope of the present claims would be readily apparent to the skilled artisan with the present application in hand. As stated above, at page 13, line 1 to page 18, line 3, Applicants provide a detailed example of how the skilled artisan may clone, express, and characterize any sequence variant to assess its standing with respect to the claimed invention. The Examiner has provided a rather nice account of some of the difficulties associated with predicting activity from

sequence and structure. However, this discourse further underscores the fact that the activity now recited in these claims provides sufficient direction with respect to the scope of these claims, as well as the importance of the disclosure of the present invention to provide the skilled artisan with express guidance to assess Na⁺/H⁺ transporter activity activity.

In fact, MPEP §2164.06 states:

... quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." In re Colianni, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

Applicants submit that, with the present specification in hand, determination of polynucleotide sequences that fall within the scope of the present invention would require nothing more than routine experimentation to determine sequence homology and protein activity. Again, the Examiner is referred to the attached sequence alignments and the discussion pertaining to the same set forth above, which clearly shows that that the skilled artisan would be able to readily assess and identify polynucleotides and polypeptides within the scope of the present invention. As such, Applicants submit that the claims of the present application are fully enabled within the context of 35 U.S.C. §112, first paragraph.

Moreover, the Examiner is reminded that the MPEP further states in §2164.02:

The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation.

Therefore, the failure to state each any every possible method by which the proteins' activities are increased, in and of itself, is not sufficient to support an enablement rejection, nor is the omission of a working example.

Also in the Office Action at the bottom of page 8, the Examiner makes a proclamation that "Applicants have not reduced to practice their invention." Applicants submit that the Examiner's proclamation is without any merit. In fact, the mere "filing of a patent application serves as conception and constructive reduction to practice of the subject matter described in the application" (MPEP § 2138.05). Moreover, MPEP §2138.05 states: "the inventor need not provide evidence of either conception or actual reduction to practice when relying on the content of the patent application."

Nonetheless, further support for the enablement of the present invention is provided by Shi et al (Nature Biotechnology, 2002), **submitted herewith**. Applicants submit that the results presented in Shi et al are in accordance with the methods set forth in the present application and provide a "proof of principal" with respect to the functionality of the claimed invention using SOS1 obtained from *Arabidopsis thaliana*. Moreover, Applicants also **submit herewith** Martinez-Atienza et al, Plant Physiol., *Conservation of the SOS Salt Tolerance Pathway in Rice*, 2006 Dec 8; [Epub ahead of print], which clearly shows that the present invention works using SOS1 sequences from rice, which are has 60% identity over the full-length sequence (see attached sequence alignment). Clearly, the present specification and the enclosed references of Shi et al and Martinez-Atienza et al demonstrate the enablement of the full scope of the claimed invention.

Based on the foregoing, Applicants submit that the present claims are fully enabled by the specification and the common knowledge available in the art and as such withdrawal of this ground of rejection is requested.

Acknowledgement that this ground of rejection has been withdrawn is requested.

The objections to the specification is obviated by appropriate amendments.
Withdrawal of this ground of objection is requested.

Applicants submit that the application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Eckhard H. Kuesters
Attorney of Record
Registration No. 28,870

Vincent K. Shier, Ph.D.
Registration No. 50,552

Customer Number

22850

(703) 413-3000
Fax #: (703)413-2220